IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 1 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE CERTAIN GENERAL OPINIONS OF MARC TOGLIA, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson submit this response in opposition to Plaintiffs' motion to exclude general opinions of Marc Toglia, M.D (Doc. 2028).

INTRODUCTION

Dr. Toglia is an internationally recognized expert in the field of urogynecology, currently serving as the Chief of Female Pelvic Medicine and Reconstructive Surgery for the Main Line Health System in Philadelphia. TVT Report (attached as Ex. B to Plaintiffs' motion) at 1; Ex. A hereto, Toglia Curriculum Vitae. He is double board certified in Female Pelvic Medicine and Reconstructive Surgery, and Obstetrics and Gynecology. TVT Report at 1. Dr. Toglia is an editor for two premier urogynecology medical journals, Female Pelvic Medicine & Reconstructive Surgery and the International Urogynecology Journal, and serves active leadership roles in the American Urogynecologic Society and the Society for Gynecologic Surgeons. *Id.* Over the course of his career, he has performed thousands of gynecologic surgeries, specifically female pelvic floor reconstruction, including native tissue repair, biological graft and synthetic mesh augmented repairs. *Id.* at 2.

Dr. Toglia began using the TVT in 1999, continues to use the product, and has performed thousands of TVT (and related SUI device) procedures as well as pelvic organ prolapse procedures. Ex. B, 3/24/16 Toglia Dep. 52:22-53:11; Ex. C, 10/02/15 Toglia Dep. 58:16-19, 64:12-14. His current practice focuses exclusively on the care of women who have urinary incontinence and pelvic floor disorders. *Id.* at 13:2-7. Dr. Toglia's decades of clinical work are supplemented by his direct involvement in research, publication and teaching. TVT Report at 1-2. He has authored a randomized clinical trial that compared the retropubic TVT with a newer sling device. He also authored a retrospective study that examined complications arising out of the use of sutures in native tissue repairs for vaginal reconstruction. *Id.* at 2; Ex. C, 10/02/15 Toglia Dep. 77:4-7, 79:8-80:11 (discussing involvement in study comparing the TVT to TVT-Secur). These studies have been presented at both national and international scientific meetings. TVT Report at 2. He has taught numerous physicians, including gynecologists, urologists and residents surgical procedures such as implantation of the TVT sling over the past two decades. *Id.* at 2; Ex. C, 10/02/15 Toglia Dep. at 217:24-218:3. This includes serving as faculty in a wide range of professional educational activities, including invited lectures, cadaver labs, as well as proctoring and preceptorships. TVT Report at 2.

As set forth below, Plaintiffs' challenges to Dr. Toglia's opinions lack merit.

ARGUMENT

I. Dr. Toglia is well qualified to provide his opinions, and his opinions are supported by reliable methodology.

A. Dr. Toglia's clinical experience is a proper basis for his opinions and is reinforced by peer-reviewed literature and other scientific evidence.

As set forth in the Introduction section above, Dr. Toglia is imminently qualified to provide expert opinions addressing the utility and safety of Ethicon's devices, and he has drawn

on his clinical and research experience in formulating his opinions. According to Plaintiffs, Dr. Toglia's opinions about the safety and efficacy of the devices at issue are unreliable because he was unable to present at his deposition patient records to confirm his account of his clinical success rate. Conspicuously absent in Plaintiffs' brief is citation to any authority that supports the proposition that Dr. Toglia was required to bring such information with him to his deposition.[1] Further, the deposition was merely for TVT and not the other devices at issue.[2]

In any event, this Court has specifically rejected Plaintiffs' same argument in this MDL litigation:

> The plaintiff takes issue with Dr. Robboy's reliance on his clinical experience because she has no way of "independently verifying" opinions. The plaintiffs argument has no practical merit. Numerous expert witnesses throughout the course of these MDLs have relied on their clinical experience in forming their expert opinions. Such practice can hardly be described as a "mystery." If *Daubert* required an expert witness to independently verify every single clinical experience he had over the course of his career, the court would never make it past pre-trial motions.

Ex. D, *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, Doc. 265, p. 40 (S.D. W. Va. Nov. 20, 2014); *see also Winebarger v. Boston Scientific Corp.*, 2015 U.S. Dist. LEXIS 53892, at *99 (S.D. W. Va. Apr. 24, 2015) (finding that expert's inability to provide "exact statistics" about the outcome of his patients did not render his personal experience opinions unreliable and that "such detail is not required under *Daubert* to opine as to '*large-scale* safety and efficacy of the Uphold device"); *Trevino v. Boston Scientific Corp.*, 2016 WL 1718836, at *33 (S.D. W. Va. Apr. 28, 2016) (same). For these same reasons, the Court should reject Plaintiffs' argument here.

[1] Although Plaintiffs requested that Dr. Toglia bring certain documents with him to his deposition, such patient records were not included as part of the request. *See* Ex. I, Deposition Notice.

[2] During his Prolift and Gynemesh PS deposition, Dr. Toglia was not asked about patient records supporting his statements, and he testified that he keeps track of prolapse patient complications through a national registry. Ex. B, 3/24/16 Toglia Dep. 54:20-55:15. Thus, the Court should limit Plaintiffs' argument to TVT.

Moreover, as detailed below, Dr. Toglia's testimony is verifiable, the rates were developed and used outside of this litigation in the normal course of his practice, and they are consistent with high-level scientific evidence that Dr. Toglia is qualified to interpret and describes at length in his reports and depositions. In preparing his reports, Dr. Toglia reviewed and referenced hundreds of scientific publications related to the safety and efficacy of the devices at issue. TVT Report generally; Ex. E, Toglia Reliance List from TVT Report. According to Dr. Toglia, he "reviewed the highest levels of evidence" that he could find. Ex. C, 10/02/15 Toglia Dep. 36:12-39:15, 322:14–324:10. He relied upon the generally accepted Level of Evidence Chart to assess and categorize the potentially relevant evidence. *Id.* at 326:24–330:12 & Ex. 17 thereto (attached as Ex. F). The Level 1 evidence included "randomized controlled trials, systematic reviews or meta-analysis," which provided a "tremendous amount of data." *Id.* at 323:6-10.[3] Additionally, he reviewed Level 2 data such as long-term registry studies and data from closed health systems, as well as societal guidelines and position statements. *Id.* at 323:15-22.

Dr. Toglia also reviewed documents provided by counsel, including internal Ethicon documents and the opinions of Plaintiffs' experts, as well as evidence relied upon by Plaintiffs' experts, such as animal studies, and hernia documents. *Id.* at 37:9–39:15, 324:1-15. As noted by Dr. Toglia, the bulk of such evidence was "Level 5 data, that you really can't draw any clinical inference or--- or application directly to" the devices. *Id.* at 324:5-10. Where the Level 5 evidence is incongruent with Level 1 evidence, the lower level evidence is significantly less useful. *Id.* at 327:11-22.

[3] As Dr. Toglia emphasized, the foundation of any systematic review, including the one he performed in reaching his opinions, is to start with the highest level of evidence. *Id.* at 327:12-16.

In addition to this thorough review and analysis of relevant scientific literature, Dr. Toglia's opinions are informed by his decades of clinical experience. As Dr. Toglia testified, the safety and utility of the devices as reflected in the literature is consistent with his clinical experience. *See, e.g.,* Ex. C, 10/02/15 Toglia Dep. at 151:22-152:9, 344:6-17. In his expert reports he described in detail reliable high level data and how it is consistent with his personal experience. *See, e.g.,* TVT Report at 17-22, 30-31. Thus, his clinical experience informs his opinion along with the scientific literature.

Moreover, his opinions regarding the safety of the product, including potential risks and complication rates, were developed independent of this litigation and are used by Dr. Toglia in the normal course of his practice. As part of his normal course of practice, Dr. Toglia informs patients regarding potential risks and complications associated with these devices, including his complication rates. Ex. C, 10/02/15 Toglia Dep. 112:8-114:4, 129:8-131:3, 336:16-337:19. These are the same rates that he testified to in this litigation when Plaintiffs questioned him regarding his practice and communications with patients. *Id.*

Dr. Toglia has tracked his patients' complication rates over time by "keep[ing] notes on the patients" and using spreadsheets. *Id.* at 336:2-15, 413:12-19. He also explained that in his hands, complication rates have been in the single digits, making it easy to recall when there are complications. *Id.* at 336:2-15. The rates he provided in his reports, and provides to his patients, are based on his "firsthand observations and tracking of complication rates over time." *Id.* at 337:20-338:8. In addition, Dr. Toglia has served as a primary investigator in a randomized trial comparing the efficacy and safety of the TVT to the TVT-Secur for the surgical treatment of SUI. Ex. A, CV at 5.

As further explained by Dr. Toglia, his rates as drawn from his extensive clinical experience are consistent with "long-term registry studies that have followed people for at least five years . . . and these are high quality, high level of evidence, or scientific papers." Ex. C, 10/02/15 Toglia Dep. 131:4-17. For example, Dr. Toglia relies on the Ogah Cochrane review which addresses multiple complications and concludes that "monofilament and macroporous mesh, like the TVT Retropubic, in the treatment of stress urinary incontinence has a lower rate of exposure than the multifilament meshes." *Id.* at 334:3-14; *see also* TVT Report at 8 (detailing Level 1 evidence including the Ogah Cochrane Review 2009). Dr. Toglia has identified additional scientific literature supporting his conclusions in his report. *Id.* at 7-24, 27-29. *See also Tyree v. Boston Scientific Corp.,* 54 F.Supp. 3d 501, 585 (S.D. W. Va. 2014) (expert applied reliable methodology supporting opinion that product was safe and effective where opinion was based upon "minimal complications in his clinical practice" which was "'on par with the findings of [the] studies' he cites throughout his expert report.")

Plaintiffs have no basis to object to Dr. Toglia's testimony regarding his clinical experience with TVT. Contrary to their argument, Dr. Toglia is not "relying solely or primarily on experience" (Doc. 2028, p. 5), but rather on experience and education combined with an extensive analysis of scientific evidence. *See Carlson v. Boston Scientific Corp.,* 2015 WL 1931311 at *35 (S.D. W. Va. Apr. 28, 2015) (allowing testimony of physician where opinions were based on scientific literature, including a published study that he conducted on the product).

B. Dr. Toglia does not intend to offer opinions about the FDA clearance process.

Citing one sentence in Dr. Toglia's report in which he observes that Plaintiffs draw their cytotoxicity claims from testing submitted during the 510(k) process, Plaintiffs ask the Court to preclude Dr. Toglia from testifying about FDA regulatory issues. TVT Report at 27. This is not

an expert opinion at all, let alone an opinion regarding the 510(k) process itself, and is not subject to *Daubert* standards. Dr. Toglia does not intend to offer any opinions at trial regarding the FDA's 510(k) clearance process.

C. The Court should allow Dr. Toglia to testify about polypropylene safety, durability and biocompatibility.

Despite Dr. Toglia's aforementioned elite qualifications as a urogynecologist, Plaintiffs claim that he is not competent to testify about polypropylene safety, durability, biocompatibility, and similar issues. Doc. 2028, p. 7. Plaintiffs' argument does not comport with Dr. Toglia's experience or with this Court's decisions.

This Court has previously found that "a urogynecologist's extensive experience with performing mesh implant and explant surgeries can qualify him or her to opine on "how the product reacts inside the body." *Winebarger,* 2015 U.S. Dist. LEXIS 53892 at *77); *see also Tyree*, 54 F. Supp. 3d at 585 (finding urogynecologist who has performed almost 3,000 sling procedures over the last twenty years qualified to testify that mesh does not shrink, contract, degrade, or cause systemic infections); *Carlson*, 2015 WL 1931311, at *9-10 (finding Dr. Galloway's clinical experience and review of the scientific literature adequately qualified him to opine on polypropylene, including its degradation, leaching, shrinkage, and contraction); *Jones v. Bard, Inc.,* No. 2:11–cv–00114, [Doc. 391], at 6–9 (finding Dr. Ostergard qualified to opine as to design); *Huskey v. Ethicon, Inc.,* 29 F. Supp. 3d 691, 734 (S.D. W. Va. 2014) (finding Dr. Johnson qualified to opine as to mesh degradation). Furthermore, in *Winebarger, supra*, the Court allowed an expert urogynecologist who was not competent to provide design opinions to testify about safety and efficacy. 2015 U.S. Dist. LEXIS 53892 at *98-100, *103-04.

Similar to the physicians in those cases, Dr. Toglia is a skilled urogynecologist with years of experience treating pelvic floor disorders, as well as the complications resulting from the

implantation of mesh. He has performed thousands of SUI and POP surgeries, using a variety of synthetic and biologic materials, and he has performed clinical studies on mesh products.

Unlike the physicians in those cases, Dr. Toglia is better suited to testify about durability, biocompatibility, and materials, because he has a degree in biochemistry, has performed chemical research, and considers himself an expert in the field. Ex. C, 10/02/15 Toglia Dep. 141:12-142:7. Indeed, he is a materials expert with a special understanding of polymer medicine as it relates to his subspecialty field, and his opinions are premised upon a thorough understanding of the interaction of living systems with permanent surgical implants, along with clinical observations from performing thousands of revision and removal procedures involving mesh. *Id.* at 144:7-15; *see also* Ex. B, 3/24/15 Toglia Dep. 120:3-23, 256:10-257:23.

Dr. Toglia's experience in the field of biomaterials includes consulting regarding the development and design of implantable surgical mesh devices. TVT Report at 2. Indeed, he was consulted on the original TVT Retropubic, Obturator and Secur devices, as well as products within the TVT Prolift family of products, and he had significant involvement in the design of the TVT-Exact product. Ex. C, 10/02/15 Toglia Dep. 72:5-14, 74:4-24; Ex. B, 3/24/15 Toglia Dep. 124:8-24. Further, Dr. Toglia was one of the surgeons who participated in the design validation of the GYNEMESH® M mesh, assessing the suitability, safety and efficacy and adequacy of the design. Ex. C, 10/02/15 Toglia Dep. 339:3-9. He has also consulted on the design and the analysis of other prototype procedures. Dr. Toglia's education, experience and review of the scientific literature adequately qualify him to opine on polypropylene, including its alleged degradation and other biomaterial properties.

In addition to challenging Dr. Toglia's qualification to opine regarding biomaterial properties, Plaintiffs wrongly criticize Dr. Toglia's methodology supporting his opinion that the

TVT mesh is a lightweight mesh, arguing that he has failed to demonstrate a "basic understanding" of the concept. Doc. 2028, p. 7. However, it is Plaintiffs who fail to understand Dr. Toglia's testimony and opinion. As Dr. Toglia explained, "weight of mesh is dependent upon the volume of surface area." Ex. C, 10/02/15 Toglia Dep. 55:16-18; TVT Report at 26. Thus, to determine whether a particular mesh product is lightweight or heavyweight, it is necessary to consider the surface area or volume. Ex. C, 10/02/15 Toglia Dep. 55:16-56:8. For the TVT product, the mesh consists of a 1.1 centimeter strip of material. *Id.* Based on this information, Dr. Toglia opines that it is lightweight mesh.[4]

Moreover, Dr. Toglia's TVT report includes multiple scientific references supporting his conclusion. TVT Report at 9-10 (citing Nilsson et al. IUJ 2013; AUGS-SUFU Position Statement on Mesh Midurethral Slings for SUI (2014)); Ex. C, 10/02/15 Toglia Dep. 57:4-22, 332:9-21 (referring to paragraph 1 of the AUGS/SUFU statement describing lightweight monofilament polypropylene sling durability, safety and efficacy including the TVT sling).

There is no merit to Plaintiffs' suggestion that certain references relied upon by Dr. Toglia in his report contradict his opinion. *See* Doc. 2028, p. 7 & n. 44. The reference cited by Plaintiffs, Costello, C.R. (2007), is the sort of case report that Plaintiffs' experts cited which Dr. Toglia had reviewed. Ex. C, 10/02/15 Toglia Dep. 37:9-39:15, 324:11-15. This case report did not involve any of the mesh devices at issue, but instead, large volume hernia mesh. Ex. G. Dr. Toglia repeatedly explained that research involving hernia mesh is lower-level evidence. TVT Report at 24-26; Ex. C, 10/02/15 Toglia Dep. 325:14-326:6. For comparison purposes, it would be difficult to compare a 1.1 cm strip of TVT mesh to a large mesh sheets, because the volume difference is so large. TVT Report at 26. Additionally, Dr. Toglia critically analyzes the medical

[4] Notwithstanding Plaintiffs' characterization of Dr. Toglia's testimony in his Gynemesh PS and Prolift deposition, Dr. Toglia merely explained that "[t]here are no established, universally accepted definitions, cutoffs, consensus of opinion." Ex. B, 3/24/16 Toglia Dep. 115:6-7.

literature and various claims regarding the biocompatibility of the TVT polypropylene mesh in his report. TVT Report at 22-29. Moreover, even it were the case that contradictory Level 1 evidence existed, such points would be grounds for cross examination, not exclusion.

Finally, Dr. Toglia is well qualified to explain to the jury that the polypropylene MSDS is not reliable for making clinical determinations. Dr. Toglia is not providing a regulatory opinion. He simply intends to explain, as a clinician with expertise in biomaterials, how and why nothing of significance may be gleaned from the MSDS. *See* Ex. C, 10/02/15 Toglia Dep. 239:7-240:10. Just because Dr. Toglia finds the MSDS to be clinically irrelevant does not mean that he is unqualified to testify about its significance. This ties into Dr. Toglia's explanation as to why it is prudent to rely on higher levels of evidence (such as Level 1 studies) in formulating clinical opinions, rather than making reckless extrapolations from sources of questionable reliability.

D. The Court should allow Dr. Toglia to testify about the risks and complication rates associated with alternative procedures.

Plaintiffs also futilely challenge Dr. Toglia's qualifications to compare TVT implants with the Burch procedure or autologous slings. Doc. 2028, p. 9. As set forth below, Dr. Toglia is well qualified to do so, and his opinions are reliable.

Dr. Toglia is a leading expert in the treatment of SUI with extensive experience in a variety of treatment procedures and products, including TVT products, Burch procedures, and autologous sling procedures. TVT Report at 2; Ex. C, 10/02/15 Toglia Dep. 184-186. He was specifically trained in both the Burch procedure and autologous sling procedures, and has used the procedures in his practice. *Id*. at 217:2-23. Although Dr. Toglia has not performed a Burch or autologous procedure in his practice in several years, he "probably revises more Burches, fascial slings, bladder neck slings than I do midurethral slings." *Id.* at 185:4-15.

Supplementing his personal experience with these procedures, Dr. Toglia has reviewed the extensive body of literature addressing the efficacy and risks of these procedures. Ex. E, TVT Report Reliance List. Plaintiffs, nevertheless, criticize Dr. Toglia because he could not break down certain Burch complication rates by sub-categories that Plaintiffs' counsel created during his deposition or cite specific references addressing these sub-categories. *See, e.g.*, Ex. C, 10/02/15 Toglia Dep. 69:12-21. Specifically, in rapid fire succession, Plaintiffs' counsel asked Dr. Toglia to identify separate rates for sub-categories of suture exposure into the vagina, bladder erosion with a Burch procedure, the incidence of vaginal exposure of suture with a Burch procedure, and urethral exposure with a Burch procedure. *Id.* at 117:1-118:24.

Although Dr. Toglia could not magically produce references addressing the isolated sub-categories of complications identified by Plaintiffs' counsel, he did refer to scientific literature supporting his opinions about complication and efficacy rates generally. As noted by Dr. Toglia in his deposition, the Schimpf systematic review and meta-analysis is Level 1 data providing information on complications and other problems that can occur with the Burch and the pubovaginal sling. *Id.* at 342:1-23. The study analyzed the number of studies and the incidence of exposure between three different types of midurethral slings: the traditional, pubovaginal and the Burch. *Id.* at 343:10-24. His TVT report further details the various studies that reflect complication rates in these procedures. TVT Report at 4-5 (citing, *inter alia*, Summit et al. 1992; Beck 1998; Bent 1993; Bryans 1979; Muznai 1992; Mundy 1993; Jarvis 1992);[5] TVT Report at 16-18 (comparing published complication rates for Burch and autologous slings with rates experienced in practice).

As set forth in Dr. Toglia's TVT report, exposure, erosion and wound complications occur with the Burch colposuspension and are higher than TVT. TVT Report at 5-6, 19-20, 31-

[5] Copies of these and any other literature referenced in this brief may be provided upon request.

32. Bladder and bowel injury, bleeding, and hematoma, with Burch and TVT occur at similar rates. *Id.* at 31. Consistent with Dr. Toglia's experience, dyspareunia/vaginal pain with TVT is rare and less than that seen with Burch and fascial sling. *Id.* at 19 (citing Schimpf et al., 2014; AUA Updated SUI Guidelines 2012). Moreover, as Dr. Toglia further explained, studies evaluating the complication rates of TVT to traditional incontinence procedures, such as the Burch colposuspension, conclude that the TVT had a lower risk of reoperation than the Burch colposuspension and a similar complication rate compared to pubovaginal sling. *Id.* at 20 (citing Novara et al., 2008).

Dr. Toglia relied upon this published data in forming his opinion, which was "consistent with [his] experience, having performed . . . each of these procedures, and also confirmed [his] experience and [his] own review of the literature of the safety and long-term efficacy" of the TVT procedure. Ex. C, 10/02/15 Toglia Dep. at 344:6-17. Dr. Toglia details the high-level evidence that supports his opinions throughout his expert report. *See, e.g.,* TVT Report at 7-16 (explaining how the literature demonstrates TVT's "slightly higher success rates, better long term durability and less associated morbidity").

In *Tyree, supra,* this Court found that a physician's inability to identify direct comparison studies of the Burch procedure and the use of slings during his deposition did not make his opinions regarding the efficacy of Burch procedure unreliable. 54 F. Supp. 3d at 522. Further, in *Carlson, supra*, this Court allowed a physician, "by way of his experience with the Uphold device and his review of the relevant scientific literature," to reliably opine how these procedures compare. 2015 WL 1931311 at *36. The Court should apply the reasoning behind those holdings here and reject Plaintiffs' objections to Dr. Toglia's opinions.

E. Dr. Toglia's opinions regarding degradation and immune response are grounded in extensive clinical experience reinforced by scientific literature.

Noting that "sub-specialty societies such as AUGS and SUFU have dismissed [concerns about alleged degradation] by pointing out that they are not supported by extensive peer reviewed literature," Dr. Toglia states in his TVT report that "my analysis of the data, including the numerous long term studies on TVT referenced in this report, leads me to conclude that the Prolene polypropylene in TVT does not degrade." TVT Report at 28; Ex. E, Reliance List. Dr. Toglia has also stated that this opinion is also based on his vast personal experience and that, even if mesh degrades, it is clinically insignificant. *Id.*; Ex. C, 10/02/15 Toglia Dep. 135:9-13, 151:22-152:5. There is no merit to Plaintiffs' argument that these opinions lack a reliable methodology. *See* Doc. 2028, p. 10.

As a threshold matter, Plaintiffs' arguments appear to be limited to Dr. Toglia's opinions about the TVT device. Because Plaintiffs present no evidence or argument about Dr. Toglia's general opinions concerning the other devices, the Court should find that Plaintiffs have only challenged Dr. Toglia's opinions about TVT.

In forming his opinions, Dr. Toglia analyzed many scientific articles, which he found consistent with his extensive clinical experience. TVT Report at 28; Ex. E, Reliance List; Ex. C, 10/02/15 Toglia Dep. 151:22-152:5, 344:6-17. As he has repeatedly testified, "there is no high-quality evidence that suggests that polypropylene degrades in the body." *Id.* at 133:23-134:1.[6] Any suggestion that mesh degrades in the body is "inconsistent with the body of Level 1

[6] In practice, Dr. Toglia routinely sends mesh specimens to the lab for identification. *Id.* at 210:13-21. Although he does not look at the slides under a microscope himself, he is familiar with what microscopic examinations of mesh look like. *Id.* at 211:2-9. He has studied them in scientific articles, which include "clear photomicrographs … with accurate pathologic descriptions" and stated that he has "an excellent working knowledge of these topics." *Id.*; Ex. C, 10/02/15 Toglia Dep. 262:21-263:15. *See also Tyree,* 54 F. Supp. 3d at 585 (simply because physician has not personally performed pathology research on polypropylene explants does not render him unqualified to testify regarding mesh shrinkage, contraction, degradation, or propensity to cause infection).

evidence and the long-term registration studies." *Id.* at 134:14-22. According to Dr. Toglia, "[t]here are no clinical concerns that that phenomenon exists." *Id.* at 135:8-13.[7]

Plaintiffs' hollow argument that Dr. Toglia cannot support his degradation opinions ignores Dr. Toglia's expert report, as well as the evidence he identified at his deposition. First, the lack of Level 1 evidence supporting a finding of clinical degradation is scientifically significant and compelling in light of the fact that mesh has been used in vivo for decades and is the "most extensively studied anti-incontinence procedure in history." TVT Report at 31; Ex. C, 10/02/15 Toglia Dep. 331:19-22.

Moreover, Dr. Toglia specifically referred to a 2001 study by Falconer that tested site-specific biopsies that demonstrated no structural degradation into the tissue surrounding implanted mesh. Ex.C, 10/02/15 Toglia Dep. 137:4-8; Ex. H, Falconer (2001). As he further explained, "[w]ithin the clinical use of the TVT for the treatment of stress urinary incontinence, there – I'm not aware of any reliable data suggesting that there is degradation." Ex. C, 10/02/15 Toglia Dep. 345:13-22.

Furthermore, Dr. Toglia adequately explained his rejection of literature cited by Plaintiffs as purportedly providing evidence of degradation. Specifically, counsel questioned Dr. Toglia regarding the Clave 2010 study, which, as Dr. Toglia opined, "would not be considered in that kind of high-level evidence analysis, in terms of clinical utility, safety or design of that device." *Id.* at 347:7-19. Dr. Toglia addressed the design limitations of the study, noting that it

[7] Plaintiffs' attempts to distinguish the Falconer study during the deposition and their brief (Doc. 2028, p. 10) provide nothing more than grounds for cross-examination. Thwarted by Dr. Toglia's ability to effectively support his opinion regarding degradation, Plaintiffs' counsel proceeded to question him regarding sub-categories of degradation that Plaintiffs' counsel could not even define to form a proper question. When Dr. Toglia explained that Falconer (2011) indeed supported the conclusion that there was no clinically significant degradation of the mesh, Plaintiffs' counsel proceeded by limiting her questions to "chemical degradation" asking Dr. Toglia if he was "aware of any studies, then that demonstrate that chemical degradation does not occur." *Id.* at 139:23-140:2. When asked by Dr. Toglia to clarify the meaning of "chemical degradation" --whether it was directed at "isomeric change in the compound" or "racemic change" or "nephelation of the compound" – Plaintiffs' counsel could not, and changed the direction of the questioning. *Id.* 141:1-142:1.

offered mere "hypotheses" regarding in vivo degradation. *Id.* at 348:17-349:5. He provided a lengthy explanation of why the study did not, and cannot, support the conclusion that degradation in vivo occurs. *Id.* at 347-352 ("[Y]ou simply can't infer. You can't clinically infer from a paper such as this, which is just sort of an observation to any kind of effect that it might have when it's used for its typical indication."). Indeed, the authors admitted that specific deteriorations correlating to implant material were not observed, and that they further acknowledge that they were unable to confirm their hypothesis concerning potential degradation, and that they were unable to determine whether the mechanical properties were altered. TVT Report at 28. Thus, Dr. Toglia's opinions about degradation are based on sound methodology.

Plaintiffs' criticisms of Dr. Toglia's opinions regarding immunologic response/foreign body reaction are similarly unfounded. Dr. Toglia repeatedly demonstrated in his testimony that the "long-term Level 1 evidence studies speak to the lack of a significant immune response." Ex. C, 10/02/15 Toglia Dep. 197:16-19. This evidence includes, "consistent with what is stated by the FDA, what is stated by NICE, what is stated by AUA, AUGS, and SUFU, that there is – that polypropylene mesh, macroporous, as used with the TVT device for its intended purpose, is the most biomechanic – biocompatible material. By definition, biocompatible speaks to host tolerance and the lack of immunologic response." *Id.* at 198:3-14.

Again, this scientific evidence is also consistent with Dr. Toglia's clinical experience. Out of 3,000 patients in which he has implanted polypropylene mesh, he has not observed one single clinical chronic foreign body reaction. *Id.* at 202:2-17, 206:14-207:11, 151:22-152:5. Dr. Toglia, who has encountered foreign body reaction with other implant material and is "very familiar with the presentation," also explained the clinical symptoms that would indicate chronic foreign body reaction. *Id* at 202:11-203:6. His experience is "consistent with the long-term

registries trials . . . that focused on the safety and looked specifically for that kind of problem." *Id.* at 151:22-152:9 (counsel statements omitted).

In fact, Dr. Toglia has published on the clinical presentations as it relates to chronic granulomatous response to a foreign body within the context of reconstructive pelvic surgery. *Id.* at 203:3-14.[8] When afforded the opportunity on cross-examination, he explained his rejection of low-level evidence that Plaintiffs suggested contradicted his conclusions. *Id.* at 353:2-354:6. Dr. Toglia noted that, in examining the literature, one must distinguish between "reactions that the body has that are of no clinical consequence, [and] reactions that the body has that could result in an adverse clinical outcome." *Id.* at 354:1-6. In evaluating Dr. Toglia's testimony, the court "must not concern [it]self with the 'correctness of the expert's conclusions' and should instead focus on the 'soundness of his methodology.'" *Id.* (citations omitted). Any alleged inconsistencies or weaknesses in Dr. Toglia's testimony go to its weight, not its admissibility. *See Daubert,* 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence").

Unlike other cases this Court has addressed, this is not a situation where there is "insufficient investigation and information to come to a conclusive determination." *See Tyree*, 54 F.Supp. 3d at 584 (rejecting expert testimony regarding adequacy of warnings that relied upon the fact that the expert simply had not personally observed certain alleged risks). Here, not only has Dr. Toglia not personally observed the risks Plaintiffs identify, he has performed an exhaustive review of the medical literature that spans decades on this particular product and has concluded, based on his expertise, that there is no reliable evidence substantiating Plaintiffs'

[8] Although Plaintiffs' counsel continually attempted to question Dr. Toglia about non-symptomatic reaction to implanted material, Dr. Toglia thoroughly explained why such reaction is not clinically significant. *See, e.g., id.* at 205:5-206:13.

claims. And, he also specifically explains his rejection of contrary claims in the literature relied upon by Plaintiffs' experts. This is sound methodology, and on multiple occasions, this Court has rejected similar arguments made by Plaintiffs and determined that a clinician expert may reliably base opinions that mesh does not degrade on the expert's clinical experience and his review of scientific literature. *See, e.g., Huskey*, 29 F. Supp. 3d at 734-35; *Carlson,* 2015 WL 1931311 at *12.[9]

F. The Court should allow Dr. Toglia to offer opinions about warnings.

Plaintiffs challenge Dr. Toglia's ability to testify about warnings, but their challenge appears to be specific to the TVT device only, and therefore, the Court should not consider Plaintiffs' argument to extend beyond TVT. Dr. Toglia has opined that the TVT IFU is clear, useful and adequate to describe the procedure and potential risks. TVT Report at 17, 32. He is familiar with IFUs through his clinical practice and professional education, and has provided consulting services assessing mesh IFUs during design validation processes. Ex. B, 3/24/16 Toglia Dep. 260:19-262:2; Ex. C, 10/02/15 Toglia Dep. 339:3-22. He has consistently reviewed the TVT IFU throughout the time he has used it "and up to the present day." *Id.* at 279:18-23.

Plaintiffs' criticisms of Dr. Toglia's warnings opinions rely upon isolated statements that are taken out of context. Doc. 2028, pp. 11-12. For instance, it is true that Dr. Toglia testified that he would not rely on Ethicon to provide him with information regarding the risks associated with the TVT device. However, as Dr. Toglia went on to explain, he does not rely on information provided by Ethicon because it is not Level 1 evidence, and he instead relies upon his own research and experience. *See, e.g.*, Ex. C, 10/02/15 Toglia Dep. 178:17-21.

[9] Finally, and in the alternative, even if Dr. Toglia were not competent to testify that TVT polypropylene mesh does not degrade, he is still well qualified to testify that there is no reliable evidence that the mesh degrades and to explain to the jury why the foundation for Plaintiffs' experts' opinions of degradation is unreliable. Opining that mesh does not degrade is altogether different than opining that there is no reliable evidence that mesh degrades or that there is no reliable evidence that any degradation has clinical significance

Similarly, although Dr. Toglia stated that he did not know what Plaintiffs' counsel meant by "complete" when counsel asked if the IFU was "complete and accurate" regarding the potential risks, it is apparent that, in text, Dr. Toglia was simply asking counsel to clarify the question so that he could understand whether he was being asked to comment on potential updates that had occurred or that might occur. *Id.* at 280:10-20. Plaintiffs also questioned Dr. Toglia about what a particular physician or patient would "want to know," to which Dr. Toglia accurately responded that he could not speak to what a particular doctor might consider relevant or would want to know. *Id.* at 269:16-17.

On the other hand, Dr. Toglia, as an experienced clinician, may testify about risks that are obvious to surgeons "in light of our education, training and experience." TVT Report at 17, 32. On pages 16-17 of his TVT report, Dr. Toglia discusses at length ordinary complications associated with SUI surgery, such as injury to vessels, infection, bleeding, scarring, voiding problems, erosion, and the need to reoperation, which are "elemental" to surgeons and need not be included in the IFU. Significantly, the law imposes no duty to warn upon sophisticated users of products with respect to risks that the sophisticated users already know or should know. *See, e.g.,* Restatement (Third) of Torts: Product Liability §2 cmt. j (1998); Restatement (Second) of the Law of Torts §402A cmt. j; American Law of Product Liability 3d §32:69 (2016); *Willis v. Raymark Indus., Inc.*, 905 F.2d 793, 797 (4th Cir. 1990). In fact, 21 CFR § 801.109(c) states there is no duty to warn if "the article is a device for which the hazards, warnings and other information are commonly known to practitioners licensed by law to use the device."

This is an objective test not dependent on the knowledge of the individual surgeon, and Dr. Toglia is certainly competent to share his opinions about what risks should be obvious to surgeons who use the devices and how an average clinician would construe the IFUs. As

reflected over pages of testimony, Dr. Toglia explained why each of the IFU disclosures was accurate based on both his experience and the Level 1 information relevant to the product. Ex. C, 10/02/15 Toglia Dep. 272-291. He detailed in his report the level of knowledge that would be expected of any surgeon performing pelvic floor surgery and reviewing the IFU, noting that "most surgical risks are common to anti-incontinence procedures as a group." TVT Report at 16-17 (citing Chahila 1999; AUA SUI Guideline 2012; AUA 2013 Position Statement; Schimpf et al, 2014). The TVT IFU supplements all the other sources of a surgeon's knowledge. *Id.* Thus, as Dr. Toglia has opined, the "IFU and Professional education for the TVT are clear, useful and adequate to describe the procedure and potential risks." *Id.*

Indeed, Ethicon writes its IFUs for pelvic floor surgeons like Dr. Toglia. Under the learned intermediary doctrine, such surgeons are the ones who must be adequately warned. If Plaintiffs intend to argue at trial that Ethicon's IFUs failed to disclose certain risks, fairness dictates that Ethicon be allowed to defend itself by demonstrating that those risks were obvious to the users of the product (pelvic surgeons and urologists), and therefore, did not need to be included in the IFU in accordance with the aforementioned law.

Ethicon recognizes that this Court has previously precluded defense experts in these cases from opining that a "warning was adequate merely because it included the risks he has observed in his own practice." *Trevino*, 2016 WL 1718836 at *45. The Court has been clear that just because an expert had not seen a particular risk in his practice did not justify his testimony that the risk did not exist. *Id*. That is not what Dr. Toglia seeks to do here, however. Instead, Dr. Toglia will testify that the complications that Plaintiffs allege should have been in the IFUs: (a) are risks that a pelvic surgeon would already know, and therefore, need not be warned about (as discussed above); (b) are not genuine complications; or (c) are not attributable to the device.

As it relates to the latter two categories, Dr. Toglia's report and deposition show that his opinions are based on his extensive clinical experience, *as well as* his thorough review of scientific literature, *and* his criticism of the literature cited by Plaintiffs' experts. *See* TVT Report at 19-28 (explaining why he disputes that mesh causes various conditions, such as particle loss, sarcomas, or degradation). Thus, this is sufficient to distinguish the circumstances in this case from *Trevino*. *See Huskey*, 29 F. Supp. 3d at 734-35 (allowing Dr. Johnson to testify about evidence of absence because his opinions were also based on medical literature); *Carlson,* 2015 WL 1931311 at *12.[10] And given the application of the learned intermediary doctrine in these cases and that Ethicon need not warn of risks known to surgeons experienced in pelvic surgery, this testimony is relevant and its admission is consistent with this Court's prior rulings.

CONCLUSION

For the reasons stated herein the Court should enter an order denying Plaintiffs' motion to limit the testimony of Dr. Toglia.

[10] While this Court has observed that "[a]bsence of evidence is not evidence of absence" *Tyree*, 54 F. Supp. 3d at 583-84, the observation only holds true where a cursory inquiry of the evidence has been made. For instance, if a physician is relying merely on his own experience to opine that a particular risk does not exist, the methodology may be flawed. However, where, as here, a physician examines the evidence outside of his own experience, such as by critiquing the medical literature and studying the conclusions of medical organizations, then the physician's opinions have a reliable basis. If there is no reliable evidence of risk as determined by a detailed review of appropriate sources, there is no obligation to include the risk in the IFU warnings.

Respectfully Submitted,

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 1 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

CERTIFICATE OF SERVICE

I, Christy D. Jones, certify that on this date, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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